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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,284	11/30/2001	Charlotte Horsmans Poulsen	674523-2012	5487

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NEW YORK, NY 10151

EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/998,284

Applicant(s)

POULSEN ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 01 November 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-4, 6, 7, 9-15, and 30-36.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


Nashaat T. Nashed, Ph. D.
Primary Examiner
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After entry of the after-final amendment filed October 28, 2004, claims 1-4, 6, 7, and 9-15, as well as new claims 30-36 will pending and under consideration.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

While the exact format of the application is not required as stated above, the various elements should be labeled and present in the specification. The application for example contains Figure 1, but it does not contain a figure description, which is required, see below for further details.

Content of Specification

- (a) **Title of the Invention:** See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

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- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the

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invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

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After entry of the after-final amendment filed October 28, 2004, the claims will be rejected as indicated below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 7, 8, 9-15, 30-32, and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed for the reasons set forth in the prior Office action, mailed November 25, 2003, and April 28, 2004.

Applicants continue to argue that disclosure describes enzymes other than hexose oxidase on page 7, lines 3-8, and that the term oxidase refers to those enzymes, which use molecular oxygen as substrate.

Applicants' arguments filed 10/28/04 have been fully considered but they are not deemed to be persuasive. While the applicants are correct of the teaching of the specification, the specification fails to identify a structural feature that is attributable to any of the stated enzymatic activities identified on page 7, line 3-8, wherein the enzyme is obtained or obtainable from a marine organism except for the hexose oxidase of SEQ ID NO: 2. While the definition of an oxidase may be debatable in what classes of enzymes may be encompassed in the term oxidases, at least claims 1-3, 6, 7, and 9-15 are not limited to oxidases. The teaching of the specification at page 3-8 is limited to oxidases, but the claims are not. In addition, the specification fails to identify the source of these enzymes, and how these enzymes can be obtained, in particular, from marine organisms. Since the applicants have not described any structural feature for any of the enzymes, in general, or any other hexose oxidase other than that of SEQ ID NO: 2, in particular, the claims remain rejected. Claims directed to a composition comprising the hexose oxidase of SEQ ID NO: 2 would overcome this rejection.

Claims 1-4, 6, 7, 9-15, 30-32, and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to an anti-fouling composition comprising *Chondrus crispus* hexose oxidase of SEQ ID NO: 2, and any of its known substrate listed in the specification for the reasons set forth in the prior Office action, mailed November 25, 2003, and April 28, 2004.

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Applicants continue to argue that disclosure enabled the claimed invention without undue experimentation.

Applicants' arguments filed 10/28/04 have been fully considered but they are not deemed to be persuasive. As indicated in the previous Office action mailed April 28, 2004, enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. Applicants have not provided any new evidence or scientific reasoning or arguments, which are sufficient to overcome a *prima facie* case of non-enablement. The scope of the claimed invention read on any composition comprising any enzyme from marine organism having any activity suitable for the claimed invention or hexose oxidase activity. Applicants seem to be confused between enzymatic activities from any source, and those isolated from marine organisms and suitable for the claimed invention. They have not identified in their specification or responses of a second enzyme that is suitable for their claimed invention from any marine organism. Once again applicants fail to explain why they consider the disclosure of the *Chondrus crispus* hexose oxidase of SEQ ID NO: 2 is sufficient enabling for any enzymatic activity, in general, and hexose oxidase, in particular, from any marine organism.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reference to amino acid sequence of "SEQ ID NO: 1" in the claim renders the claim indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. SEQ ID NO: 1 is a nucleic acid sequence, which encodes the amino acid sequence of SEQ ID NO: 2. For examination purposes only, it is assumed that the applicant is referring to SEQ ID NO: 2 only.

Applicants thought that they have overcome this rejection by canceling claims 5, 22, 24, 26, 28, and 29. The rejection remains on record because applicants have reintroduced the phrase in new claim 33.

The following is a quotation of 35 U.S.C. 103, which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-4, 6, 7, 9-15, and 30-36 are rejected under 35 U.S.C. 103 as being unpatentable over (IDS: reference AF, EP-0866103 A1) in view of Hansen *et al.* [J. Biol. Chem. 272 (17), April 25, 1997, pages 11581-11587] for the reasons set forth in the prior Office action, mailed November 25, 2003 and April 28, 2004.

Claims 1-4, 6, 7, 9-15, 30-32 and 33-36 are rejected under 35 U.S.C. 103 as being unpatentable over Hamade *et al.* (IDS: reference AF, EP-0866103 A1) in view of U. S. Patent 6,251,626 B1 [626 patent, Stougaard *et al.*] for the reasons set forth in the prior Office action, mailed November 25, 2003, and April 28, 2004.

In response to the above rejections, Applicants argue that Hamade *et al.* does not teach that the substrate of said oxidase could be produced within composition by a second enzyme action on a precursor substrate such as the action of cellulase on cellulose to produce glucose. Also, Dr. Charlotte Paulson filed a declaration on October 28, 2004, giving here interpretation of the teachings of Hamade *et al.*

Applicants' arguments and Dr. Paulson declaration filed 10/28/04 have been fully considered but they are not deemed to be persuasive. The applicants and the examiner should agree on two facts: (1) the word cellulose does not appear nowhere in Hamade *et al.*, and (2) the rejections stated above are not made under 35 U. S. C. 102. Also, we should agree that Hamade *et al.* teach an antifouling composition comprising hexose oxidase, see page 5 on line 18. Hamade *et al.* teach that the substrate for the enzyme that produces the antifouling agent such as hydrogen peroxide could be produced by the action of a second enzyme, see page 3 on lines 38-46. They exemplified their invention with the production of glucose by the action chitosanase or cellulase on chitosan at page 5 on lines 52-53. Thus, Hamade *et al.* teach the claimed invention,

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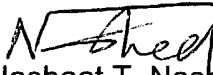
except that the second enzyme is not taught to be from a marine organism. Hansen *et al.* and Stougaard *et al.* remedy the deficiency of Hamade *et al.* by teaching the hexose oxidase from the marine algae *Chondrus crispus*, and provide a motivation to use said enzyme as they teach that the wide substrate specificity of hexose oxidase provides a greater applicability. Also, other motivation of using hexose oxidase is its higher affinity for glucose, 10-fold higher than glucose oxidase, see page 11586, left column, first paragraph of the discussion section. As previously pointed out in the Office action mailed November 25, 2003, the action of amyloglucosidase on its substrates such as starch is well known to produce glucose, it would have been obvious to use the amyloglucosidase and starch as combination to produce glucose in the composition taught by Hamade *et al.* The examiner assertion that the action of amyloglucosidase on its substrates is well known to produce glucose has never been challenged by the applicants, and therefore, is an accepted fact by the applicants. Thus, one of ordinary skill in the art would have had the teaching of the cited prior art, the motivation to use a superior oxidase also taught in the prior art, and reasonable expectation of success, which comes from the teachings of Hamade *et al.*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Nashaat T. Nashed, Ph. D.
Primary Examiner
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